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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,744	07/20/2000	HISAYOSHI SHIMIZU	2501USOP	1419

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TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/600,744

Applicant(s)

SHIMIZU ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-10 and 13-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-10 and 13-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Receipt is acknowledged of the Information Disclosure Statement and the Amendment B, both received November 27, 2001.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, and 8-10, 13, 15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 394 050 A2 to Ueda *et al.*. Ueda *et al.* disclose a method of preparing a freeze dried preparation in which a first liquid is frozen, a second liquid is added to the frozen first liquid, and the frozen first and second liquids are freeze dried together, wherein one of the two liquids contains a pharmaceutically active compound or a preparation dissolved or suspended therein (p 11, claim 1). Ueda *et al.* further teach that the process takes place in a container (p 4, l 11). Claim 9 of the reference teaches that the liquids are frozen at temperatures of between –10 and –50°C. Example 5 of reference 1 teaches applicant's method of coating the inside of a container (vial) with ice, and then proceeding with the freeze drying steps. The teachings of Ueda *et al.* anticipate the limitations of applicant's above listed claims.

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Applicant's arguments filed November 27, 2001 have been fully considered but are not found to be persuasive. Applicant argues that the newly amended claims required that the process produce microspheres. Applicant further argues that the cited reference does not refer to microspheres. However, it is the position of the examiner that lyophilization (Freeze drying) is a well known process which is practiced routinely in the scientific and pharmaceutical areas. The process of lyophilization results in the formation of a porous sheet at the bottom of the container when the solvent is removed. Once the porous sheet is scraped from the container, a powder results. It is the position of the examiner that the cited reference teaches the same process as claimed by applicant, and therefore the resultant product is the same. The burden is shifted to applicant to supply any comparative data showing that the resultant product achieved by applicant is different than the product achieved by the cited reference. For these reasons, this rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-10, and 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 394 050, as discussed above, and in view of the following comments.

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Ueda *et al.* do not specifically teach that the resultant product be microspheres.

However, it is the position of the examiner that the process of freeze drying is well known in the art. This process results in a porous sheet at the bottom of the freeze drying contained. Upon scraping the sheet, a powder is formed. It is the position of the examiner that there is no patentable distinction between the resultant product of applicant and the resultant product of the cited art. Furthermore, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Ueda *et al.* do not specifically disclose a layer of a water repelling substance. However, Ueda *et al.* do teach the used of at least two frozen layers of different liquids (p 3, l 55-57). Based on the generic teachings of Ueda *et al.*, one of ordinary skill in the art would have been motivated to perform the freeze drying process by lining a container (such as a vial) with ice, and an additional layer of a different liquid, and then proceeding with the freeze drying steps. There are no limitations in Ueda *et al.* as to what the second liquid may be. However, Ueda *et al.* do teach that one of the layers contains a pharmaceutical active suspended or dissolved therein (p 3, l 35-36).

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Therefore, it is the position of the examiner that if the desired active for the formulation is a hydrophobic active, then the skilled practitioner would use a hydrophobic layer in addition to the ice layer. If the desired active for the formulation is hydrophilic, the skilled practitioner could place the active in the water-ice layer, or use a hydrophilic liquid as the second layer. Either way, one of ordinary skill in the art would have been motivated to use either a hydrophobic or hydrophilic layer as the second layer to be frozen in the container. The expected result would be a pharmaceutically acceptable lyophilized formulation.

Additionally, the purpose of applicant's claimed invention is to supply a process with a better yield of microspheres, with a reduced risk for entry of foreign substances. These are the same problems addressed in the Ueda *et al.* disclosure. Ueda *et al.* teach that their invention overcomes problems such as contamination, as well as faster and better recovery (p 3, l 1-35). Therefore, absent any evidence to the contrary, applicant's claimed invention achieves the same goal as that of the prior art, with no unexpected results. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been considered but are not found to be persuasive for the reasons recited above. Therefore, this rejection is maintained.

Conclusion

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600